MAR 1 5 2001

III. Summary of Safety and Effectiveness

The ACON One Step Marijuana Test is a qualitative screening rapid chromatographic immunoassay based on the principle of competitive binding. The test utilizes a monoclonal antibody to selectively detect elevated levels of marijuana in urine at a cut-off concentration of 50ng/mL. Drugs which may be present in the urine specimen compete against the drug conjugate for binding the sites on the antibody.

During testing, a urine specimen migrates along the strip by capillary action. Marijuana, if present in the urine specimen below 50 ng/ml, will not saturate all of the binding sites of the antibody-coated particles in the test strip. The antibody-coated particles will then be captured by immobilized marijuana conjugate coated on the strip and a visible colored line will show up in the test line region. The colored line will not form in the test region if the marijuana level is above 50 ng/ml because it will saturate all of the binding sites of the anti-marijuana antibody-coated particles.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug negative urine specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

A three way side-by-side comparison was conducted using the ACON THC One Step Marijuana Test Strip (Urine), ACON THC One Step Marijuana Test Device (Urine) and the LifeSign Status-DS THC Test. Testing was performed on specimens previously collected from subjects presenting for Drug Screen Testing. The Syva Emit II Cannabinoid Assay was used as an initial screen to identify positive specimens. Presumptive positive results were confirmed by Gas Chromatography / Mass Spectrometry. The following results were obtained:

		Life Sign +	Life Sign -
ACON Strip	+	140	0
ACON Strip	-	3	157

Percent Negative Agreement: > 99%
Percent Negative Agreement: 98%
Overall Agreement: 99%

		Life Sign +	Life Sign -
ACON Device	+	143	0
ACON Device	-	0	157

Percent Negative Agreement: > 99%
Percent Negative Agreement: > 99%
Overall Agreement: > 99%

The ACON THC One Step Marijuana Test Device demonstrated 100% agreement with the LifeSign Status-DS THC Test while the ACON THC One Step Marijuana Test Strip demonstrated 99% agreement with the the LifeSign Status-DS THC.

Nora C.R. York — 2/5/01

Nora C.R. York — Date

ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

K003557

Premarket Notification 510(k) Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 5 2001

Ms. Nora C.R. York
Manager, Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd
San Diego, CA 92121

Re: K003557
Trade Names: ACON® THC One Step Marijuana Test Strip (Urine) and ACON® THC One Step Marijuana Test Device (Urine)
Regulatory Class: II
Product Code: LDJ
Dated: February 5, 2001
Received: February 7, 2001

Dear Ms. York:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

IV. Indications for Use

510(k) Number: K003557

Device Name: ACON® THC One Step Marijuana Test Strip (Urine)
ACON® THC One Step Marijuana Test Device (Urine)

"Indications For Use": The ACON® THC One Step Marijuana Test Strip (Urine) and the ACON® THC One Step Marijuana Test Device (Urine) are qualitative screening rapid chromatographic immunoassays intended for the use of detecting THC metabolites in human urine at a cutoff concentration of 50ng/mL. These tests are indicated for professional use only.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003557

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use ____

(per 21 CFR 801.109)